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**JONELLE KIRKPATRICK**

UNITED STATES DISTRICT COURT

DISTRICT OF HAWAII

JONELLE KIRKPATRICK,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,  
INC.; TEVA WOMEN'S HEALTH,  
INC. d/b/a TEVA WOMEN'S  
HEALTH, LLC; TEVA WOMEN'S  
HEALTH, LLC; THE COOPER  
COMPANIES, INC.; and  
COOPERSURGICAL, INC.,

Defendants.

Case No.:

**COMPLAINT; DEMAND FOR  
JURY TRIAL; SUMMONS**

## **COMPLAINT**

COMES NOW Plaintiff Jonelle Kirkpatrick (“Plaintiff”), by and through its attorneys, CASE LOMBARDI & PETTIT, a Law Corporation, and SANDERS PHILLIPS GROSSMAN, LLC., files this Complaint against Defendants Teva Pharmaceuticals USA, Inc., Teva Women’s Health, Inc. doing business as Teva Women’s Health, LLC, Teva Women’s Health, LLC, The Cooper Companies, Inc., and Cooper Surgical, Inc. (collectively hereinafter “Defendants”), both jointly and severally, as the companies and/or successors in interest to the companies that designed, developed, manufactured, tested, labeled, packaged, distributed, marketed and/or sold the ParaGard Intrauterine medical device that was implanted into Plaintiff, and throughout the United States. Accordingly, Plaintiff alleges and states as follows:

### **I. INTRODUCTION**

1. This is an action for damages relating to the Defendants’ design, manufacture, surveillance, sale, marketing, advertising, promotion, labeling, packaging, and distribution of ParaGard Intrauterine medical device (hereinafter “ParaGard IUD”).

2. The ParaGard IUD is an intrauterine device, however, it is regulated as a drug. It is placed into the uterus to prevent conception.

3. The ParaGard IUD has a propensity to break at the arms upon explant resulting in serious injuries.

4. Plaintiff used the ParaGard IUD, and as a result of its use suffered injuries.

## **II. GENERAL ALLEGATIONS**

5. Plaintiff by and through Plaintiff's attorneys, CASE LOMBARDI & PETTIT, A Law Corporation, and SANDERS PHILLIPS GROSSMAN, LLC., brings this action for personal injuries suffered as a result of using the defective and dangerous ParaGard IUD.

6. The ParaGard IUD is prescribed to prevent conception, and at all times relevant hereto, were manufactured, designed, tested, packaged, labeled, marketed, advertised, promoted, distributed, and sold by Defendants. On information and belief, Plaintiff used the ParaGard IUD resulting in injuries.

## **III. PARTIES**

7. At all times relevant to this action, Plaintiff, was an individual, citizen and resident of the state of Hawaii.

8. Plaintiff was implanted with the ParaGard IUD in 2010. It was removed in 2019, resulting in injuries.

9. Defendant Teva Pharmaceuticals USA, Inc. (hereinafter "Teva Pharmaceuticals" or "Teva USA") is a Delaware corporation with headquarters

located at 1090 Horsham Rd. in North Wales, Pennsylvania. At times relevant to this action, Teva USA designed, developed, manufactured and marketed the ParaGard IUD at issue. At times relevant to this action, Teva USA communicated with the United States Department of Health and Human Services, Food and Drug Administration (hereinafter “FDA”) regarding the sale, use, and safety concerns related to ParaGard IUDs, which includes managing product recalls, investigating adverse events from ParaGard IUD users, and performing mandatory reporting to FDA regarding the ParaGard IUD.

10. At times relevant to this action, Teva USA was involved in regulatory communications, and medical communications, including but not limited to communications with physicians, doctors, the FDA and other medical personnel, which led to activities giving rise to failure to warn, negligence, gross negligence, common law fraud, negligent misrepresentation, breach of warranty, and a violation of consumer protection laws.

11. Defendant Teva Women’s Health, Inc., is a Delaware corporation with headquarters located at 425 Privet Rd., in Horsham, Pennsylvania and is and/or was a wholly owned subsidiary of Teva USA, and/or operated as a successor-in-interest to Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., and/or assumed Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., in a name change after its acquisition by Teva USA. Teva Women’s Health, Inc.

converted into Teva Women's Health, LLC in 2017 and continues to operate as Teva Women's Health, LLC. At times relevant to this action, Teva Women's Health, Inc. designed, developed, manufactured and marketed the ParaGard IUD at issue.

12. Defendant Teva Women's Health, LLC is a Delaware limited liability company with headquarters located at 425 Privet Rd., in Horsham, Pennsylvania and is and/or was a wholly owned subsidiary of Defendants Teva Pharmaceuticals. Teva Women's Health, LLC is the product of an entity conversion pursuant to Del. Code Ann. Tit. 8, 266. Teva Women's Health, Inc., converted into Teva Women's Health, LLC and continues to operate as a limited liability company instead of an incorporation (Teva Women's Health, LLC formerly known as Teva Women's Health, Inc. collectively hereinafter "Teva Women's Health").

13. Accordingly, Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., d/b/a Teva Women's Health Inc., (hereinafter "Duramed"), acquired FEI Women's Health in 2005 wherein the asset of ParaGard IUD was acquired in the deal. Duramed was acquired by Teva USA in 2008 wherein its name was changed to Teva Women's Health, Inc., a wholly-owned subsidiary of Teva USA. (Defendants Teva USA and Teva Women's Health collectively hereinafter "Teva Defendants").

14. Defendant The Cooper Companies, Inc., (hereinafter "Cooper Companies") is a Delaware corporation with headquarters at 6140 Stoneridge Mall

Rd., in Pleasanton, California. Cooper Companies purchased assets and global rights and business of the ParaGard IUD in September 2017 for \$1.1 Billion, including their manufacturing facility in Buffalo, New York.

15. Defendant CooperSurgical, Inc., (hereinafter “Cooper Surgical”) is a Delaware corporation with headquarters at 95 Corporate Dr. in Trumbull, Connecticut and a subsidiary of Defendant Cooper Companies (Defendants Cooper Companies and CooperSurgical collectively hereinafter “Cooper Defendants”).

16. At all times relevant hereto and alleged herein, the Defendants conducted and continues to conduct substantial business within the State of Hawaii, and within the District of Hawaii.

17. At times relevant hereto and alleged herein, the Defendants conducted and continues to regularly conduct substantial business within the State of Hawaii, which included and continues to include, the research, safety surveillance, manufacture, sale, distribution and marketing of the ParaGard IUD, which is distributed through the stream of interstate commerce into the State of Hawaii, and within the District of Hawaii,

18. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other.

19. The Cooper Defendants are liable as successors-in-interest under the Hawaii Uniform Fraudulent Transfer Act, Haw. Rev. Stat. §651C-1, *et. seq.*, any

other state or federal successor in interest acts or statutes; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

20. Upon reasonable belief, Duramed became Teva Women's Health, Inc., through a name change in 2008. Teva Women's Health, Inc., then became Teva Women's Health, LLC through a conversion in 2017. Teva Women's Health, LLC then sold all of its assets including the ParaGard IUD to the Cooper Defendants in 2017. Teva Women's Health, LLC became a *holdings* company with no tangible assets.

21. The Cooper Defendants knew or should have known that the transfer and conversion of Teva Women's Health, Inc, was intended to thwart potential creditors from having a claim against Teva Women's Health, Inc. or Teva Women's Health, LLC. Therefore, the Cooper Defendants are liable pursuant to the Federal Consumer Protection Acts and Hawaii Uniform Fraudulent Transfer Act, Haw. Rev. Stat. §651C-1, *et. seq.*

22. The liability of these companies has passed on through various business instruments and now lies with both the Teva Defendants and the Cooper Defendants.

23. At times relevant and material hereto, Defendants were engaged in the business of, or were successors-in-interest to entities engaged in the business of, researching, developing, designing, formulating, licensing, manufacturing, testing, producing, processing, assembling, packaging, inspecting, distributing, selling,

labeling, monitoring, marketing, promoting, advertising, and/or introducing into interstate commerce throughout the United States, and in the State of Hawaii, and within the District of Hawaii, either directly or indirectly, through third-parties, subsidiaries and/or related entities, the ParaGard IUD, a drug used in the prevention of pregnancy, implanted in patients throughout the United States, including Plaintiff.

24. At all times alleged herein, Defendants were authorized to conduct or engage in business within the State of Hawaii and supplied the ParaGard IUD within the State of Hawaii and the District of Hawaii. Defendants received financial benefit and profits as a result of designing, manufacturing, marketing, advertising, selling and distributing the ParaGard IUD within the State of Hawaii, and the District of Hawaii.

25. The combined acts and/or omissions of each Defendant resulted in indivisible injuries to Plaintiff. Each of the above-named Defendants is a joint tortfeasor and/or co-conspirator and is jointly and severally liable to Plaintiff for the negligent acts and omissions alleged herein. Each of the above-named Defendants directed, authorized or ratified the conduct of each and every other Defendant.

26. The amount in controversy exceeds the jurisdictional limits of this court.

#### **IV. JURISDICTION AND VENUE**

27. Plaintiff incorporates by reference all of the above paragraphs.



28. Jurisdiction is proper in this court pursuant to 28 U.S.C. § 1332 as complete diversity of citizenship exists between Plaintiff and Defendants and the matter in controversy exceeds the sum of \$75,000.00, exclusive of interest and costs.

29. This Court has jurisdiction over the non-resident Defendants because they have conducted business in the State of Hawaii. Defendants have committed a tort in whole or in part in the State of Hawaii and have regular and continuing contacts with Hawaii.

30. In addition, venue of this case is proper in the State of Hawaii pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred in the District of Hawaii.

## **V. FACTUAL ALLEGATIONS**

31. The ParaGard IUD is an intrauterine drug that can provide long term birth control, up to 10 years, without hormones.

32. The ParaGard IUD drug is a T-shaped plastic frame made of polyethylene and barium sulfate that is inserted into the uterus. Copper wire coiled around the IUD produces an inflammatory reaction that is toxic to sperm and egg. A monofilament polyethylene thread is tied through the tip, resulting in two white threads, which aid in the detection and removal of the drug.

33. The ParaGard IUD has a propensity to break at the arms upon explant resulting in serious injuries.

34. At relevant times, Teva Defendants designed, researched, manufactured, labeled, packaged, promoted, marketed and/or sold the ParaGard IUD at issue after receiving New Drug Application approval from FDA.

35. In 2008, Teva USA became the owner of the ParaGard IUD when it acquired Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., through its purchase of Barr Pharmaceuticals, Inc.

36. Upon information and belief, when Teva USA acquired Duramed, a division of Barr Pharmaceuticals, Inc., it also acquired Duramed's manufacturing facilities, sales force and responsibility for maintaining and updating the labeling for ParaGard IUD.

37. Shortly thereafter, Teva USA changed the name of Duramed Pharmaceuticals, Inc., a division of Barr Pharmaceuticals, Inc., to Teva Women's Health, Inc., a wholly owned subsidiary of Teva USA.

38. On August 31, 2009, Duramed Pharmaceuticals, Inc., filed with the Ohio Secretary of State a Certificate of Amendment to Foreign Corporation Application For License requesting a name change. A new entity was not created, and no entities were dissolved. Duramed's license number did not change. Instead, Duramed changed its name to Teva Women's Health, Inc.

39. Upon information and belief, Teva Women's Health, Inc. is simply a new name for Duramed.

40. Upon information and belief, and for purposes of liability and interest, Teva Women's Health, Inc., is the same entity as Teva Women's Health, LLC. Teva Women's Health, Inc., converted into Teva Women's Health, LLC under the laws of Delaware. Del. Code Ann. Tit. 8, 266. Pursuant to Del. Code Ann. Tit. 8, 266, a company that converts from one entity into another is deemed to be a continuation of the preexisting company. A conversion does not equate to a dissolution and no winding up takes place. Therefore, Teva Women's Health, Inc., did not dissolve, windup, or *cease to exist* and liability continues from the corporation to the Limited Liability Company.

41. Upon information and belief on August 11, 2017, Teva Women's Health, Inc., converted into Teva Women's Health, LLC and sold off all of its assets.

42. On September 11, 2017, Teva Defendants sold the ParaGard IUD to Cooper Defendants.

43. ParaGard IUD is currently sold only in the U.S. and had earned revenues of approximately \$168 million for the twelve-month period ending June 30, 2017.

44. The Cooper Defendants still manufacture and sell the ParaGard IUD in the U.S.

45. The ParaGard IUD was marketed heavily by Defendants as being safe and effective, and promising fewer side effects than other birth control methods.

46. The marketing and promotional efforts of Defendants, their advertisers, and sales force served to overstate the benefits of ParaGard IUD and minimize and downplay the risks. These promotional efforts were made while Defendants fraudulently withheld important safety information from health care providers and the public.

47. Prior to Plaintiff being implanted with the ParaGard IUD, Defendants knew and should have known that the drug was defective and unreasonably dangerous.

48. Defendants knew or should have known that ParaGard IUD can and does cause serious harm to individuals who use it, due to the risk of the ParaGard IUD's arm breaking upon removal.

49. Defendants knew of these risks from the trials they performed, their post-marketing experience and complaints, third party studies, and their own analysis of these studies, but took no action to adequately warn or remedy the defects and instead concealed, suppressed and failed to disclose or fix this danger.

50. The product warnings for ParaGard IUD were vague, incomplete or otherwise wholly inadequate to alert prescribing physicians and patients to the actual risks associated with ParaGard IUD.

51. Defendants' marketing and promotion, through its own website, sought to reassure physicians and patients of Defendants' longstanding record of quality and safety assurance.

52. Based upon these representations, upon which Plaintiff and her physician relied, Plaintiff had the ParaGard IUD implanted, believing it would be safe and effective, for the entire duration it was implanted and upon removal.

53. Since 2010, the FDA has received over 1600 reports of ParaGard IUD breakage, with over 700 classified as serious.

54. Defendants failure to adequately communicate and report to the FDA the injuries associated with ParaGard IUD resulted in inadequate warnings.

55. The Cooper Defendants are also liable as successors-in-interest under the Hawaii Uniform Fraudulent Transfer Act, Haw. Rev. Stat. §651C-1, *et. seq.*, any other state or federal successor in interest acts or statutes; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

## **VI. PLAINTIFF'S USE OF PARAGARD IUD**

56. On information and belief, in July 1, 2010, Plaintiff was implanted with Defendants' ParaGard IUD by Roxanne Estes, CNM at Pahoehoe Women's Health Center.

57. Plaintiff, a young and healthy woman, wanted a ParaGard IUD because it was a reversible form of birth control that would allow her to conceive in the future.

58. In or about June 4, 2019, Plaintiff went to have the ParaGard IUD removed in Bay Clinic Inc. - Pahoia Family Health Center by Naomi Whitaker, APRN.

59. Naomi Whitaker, APRN attempted to remove the ParaGard IUD as instructed by Defendants, by grasping the ParaGard IUD and pulling gently. Despite following the instructions provided by Defendants, a ParaGard IUD arm was retained. Naomi Whitaker, APRN attempted to remove the retained arm of the ParaGard IUD without success.

60. On information and belief, in June 6, 2019, Plaintiff had an ultrasound that confirmed the location of the ParaGard IUD arm in the cervix.

61. On or about June 20, 2019, Celeste S. Adrian, MD attempted to remove the retained ParaGard IUD arm via hysteroscopy without success.

62. Prior to her procedures, Plaintiff and her doctors were provided with no warning from the Defendants of the risk of ParaGard IUD failure and injury, nor were Plaintiff and her doctors provided with adequate warning of the risk of removal of ParaGard IUD. This information was known or knowable to the Defendants.

63. On information and belief, Plaintiff used the ParaGard IUD manufactured, packaged, marketed, sold and/or distributed by Defendants. The ParaGard IUD reached Plaintiff without substantial change in the drug's condition.

64. On information and belief, as a direct and proximate result of using ParaGard IUD, Plaintiff developed serious and/or permanent adverse effects.

65. As a result of said injuries, Plaintiff suffered significant bodily and mental injuries, pain and suffering, mental anguish, disfigurement, embarrassment, inconvenience, loss of earnings and earning capacity, and have and will incur past and future medical expenses.

66. At all relevant times, each Defendant had knowledge that there was a significant increased risk of adverse events associated with ParaGard IUD including arm breakage, and despite this knowledge Defendants continued to manufacture, market, distribute, sell, and profit from sales of ParaGard IUD.

67. The Cooper Defendants continue to manufacture, market, distribute, sell and profit from sales of ParaGard IUD.

68. Despite such knowledge, Defendants knowingly, purposely, and deliberately failed to adequately warn Plaintiff, patients, consumers, medical providers, and the public of the increased risk of serious injury associated with using ParaGard IUD.

69. On information and belief, Plaintiff's prescribing physicians would not have prescribed ParaGard IUD to Plaintiff, would have changed the way they warned Plaintiff about the signs and symptoms of serious adverse effects of ParaGard IUD, and discussed with Plaintiff the true risks of arm breakage and resulting injuries and complications had Defendants provided said physicians with an appropriate and adequate warning regarding the risks associated with the use of the ParaGard IUD.

70. As a direct and proximate result of Defendants' conduct, Plaintiff suffered injuries, including, but not limited to, pain, suffering, and loss of reproductive health, which resulted in damages to Plaintiff in a sum in excess of the jurisdictional limits of the Court.

71. The Defendants maintained a duty to Plaintiff after the ParaGard IUD was implanted and until it was removed.

72. The Cooper Defendants are also liable as successors-in-interest under Hawaii Uniform Fraudulent Transfer Act, Haw. Rev. Stat. §651C-1, *et. seq.*, any other state or federal successor in interest acts or statutes; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

73. As a direct result of Plaintiff's use of the ParaGard IUD, Plaintiff suffered from having a broken arm of the ParaGard IUD in her, causing her damage, including but not limited to pain, suffering, mental anguish, the loss of reproductive



health, loss of enjoyment of life, medical expenses and other out of pocket losses and loss of income.

## **VII. DELAYED DISCOVERY**

74. Plaintiff incorporates by reference the factual portion of this Complaint as if fully set forth herein and additionally, or in the alternative, if same be necessary, allege as follows:

75. Plaintiff plead that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiff had been injured, the cause of the injury and the tortuous nature of the wrongdoing that caused the injury.

76. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relation to the Plaintiff's ParaGard IUD and Defendants' wrongful conduct was not discovered and could not have been discovered, until a date within the applicable statute of limitations for filing each of Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

77. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by the Defendants when

they had a duty to disclose those facts. The Defendants' purposeful and fraudulent acts of concealment have kept Plaintiff ignorant of vital information essential to the pursuit of Plaintiff's claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's filing of their causes of action. The Defendants' fraudulent concealment did result in such delay.

78. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of their ParaGard IUD.

## **VIII. CAUSES OF ACTION**

### **COUNT I – NEGLIGENCE**

79. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

80. At times relevant, Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling and/or distributing the ParaGard IUD, including the one that was implanted into the Plaintiff.

81. Defendants had a duty to exercise reasonable and ordinary care in the manufacture, design, labeling, instructions, warnings, sale, marketing, safety surveillance and distribution of the ParaGard IUD so as to avoid exposing others to foreseeable and unreasonable risks of harm.

82. Defendants breached their duty of care to the Plaintiff and her physicians, in the manufacture, design, labeling, warnings, instructions, sale, marketing, safety surveillance, and distribution of the ParaGard IUD.

83. Defendants knew that the ParaGard IUD could break upon removal and failed to warn Plaintiff of this potential injury.

84. Defendants had a duty to warn Plaintiff, Plaintiff's physician, and/or the medical community of the potential for breakage at the arm(s) upon removal.

85. Defendants knew or reasonably should have known that the ParaGard IUD was dangerous or likely to be dangerous when used in its intended or reasonably foreseeable manner.

86. At the time of the manufacture and sale of the ParaGard IUD, Teva Defendants knew or should have known that the ParaGard IUD was designed and manufactured in such a manner so as to present an unreasonable risk of the fracture of the arm of the drug upon removal.

87. At the time of the manufacturer and sale of the ParaGard IUD, Teva Defendants knew or should have known that the ParaGard IUD was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement and subsequent removal.

88. At the time of the manufacture and sale of the ParaGard IUD, Teva Defendants knew or should have known that using the ParaGard IUD for its intended

use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe injuries, including but not limited to additional surgeries and/or medical procedures in order to remove the fragmented drug, even leading to hysterectomy.

89. Upon acquisition of ParaGard IUD from Teva Defendants, Cooper Defendants are charged with the same knowledge that Teva Defendants knew or should have known regarding the risks associated with ParaGard IUD at the time of manufacture and sale, and therefore, all Defendants had a continuing duty to warn Plaintiff and her physicians or the general health care community of those reasonably known risks.

90. Defendants knew or reasonably should have known that the consumers of the ParaGard IUD would not realize the danger associated with using the drug for its intended use and/or in a reasonably foreseeable manner.

91. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the ParaGard IUD in, among others, the following ways:

- a. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other drug available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications;

d. Failing to use reasonable care to warn or instruct Plaintiff, Plaintiff's healthcare providers or the general health care community about the ParaGard IUD's substantially dangerous condition or about facts making the product likely to be dangerous, including pre-and post-sale;

e. Failing to perform reasonable pre-and post-market testing of the ParaGard IUD to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, to those persons to whom it was reasonably foreseeable would recommend, use, implant and remove the ParaGard IUD;

g. Advertising, marketing and recommending the use of the ParaGard IUD, while concealing and failing to disclose or warn of the dangers known by the Defendants to be connected with and inherent in the use of the ParaGard IUD;

h. Representing that the ParaGard IUD was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the ParaGard IUD with the knowledge that the IUD was dangerous and not reasonably safe, and failing to comply with the FDA good manufacturing regulations;

j. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the ParaGard IUD so as to avoid the risk of serious harm associated with the use of the IUD;

k. Failing to establish an adequate quality assurance program used in the manufacturing of the ParaGard IUD;

l. Failing to establish and maintain an adequate post-marketing surveillance program for the ParaGard IUD;

m. Failing to adequately and correctly report safety information relative to the ParaGard IUD product resulting in inadequate warnings; and

n. Failing to provide adequate and continuous warnings about the inherent danger of breakage with the ParaGard IUD upon removal.

92. A reasonable manufacturer, distributor, and/or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

93. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the ParaGard IUD, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

94. The Cooper Defendants are also liable as a successors-in-interest under the Hawaii Uniform Fraudulent Transfer Act, Haw. Rev. Stat. §651C-1, *et. seq.*, any other state or federal successor in interest acts or statutes; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

## **COUNT II – STRICT LIABILITY DESIGN DEFECT**

95. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

96. The ParaGard IUD is inherently dangerous and defective, unfit and unsafe for its intended use and reasonably foreseeable uses and does not meet or perform to the expectations of patients and their health care providers.

97. The ParaGard IUD was expected to, and did, reach its intended consumer without substantial change in the condition in which it was in when it left Defendants' possession.

98. The ParaGard IUD implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the products would have expected at time of use.

99. The ParaGard IUD implanted in Plaintiff was defective in design, in that the IUD's risks of harm exceeded its claimed benefits.

100. Plaintiff and her healthcare providers used the ParaGard IUD in a manner that was reasonably foreseeable to the Defendants.

101. Neither Plaintiff nor her healthcare providers could have by the exercise of reasonable care discovered the IUD's defective conditions or perceived its unreasonable dangers prior to her implantation of the drug.

102. As a result of the foregoing design defects, the ParaGard IUD created risks to the health and safety of its users that were far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the ParaGard IUD.

103. Defendants have intentionally and recklessly designed the ParaGard IUD with wanton and willful disregard for the rights and health of the Plaintiff and



others, and with malice, placing their economic interests above the health and safety of the Plaintiff and others.

104. As a proximate result of the Defendants' design of the ParaGard IUD, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

105. The Cooper Defendants are also liable as successors-in-interest under the Hawaii Uniform Fraudulent Transfer Act, Haw. Rev. Stat. §651C-1, *et. seq.*, any other state or federal successor in interest acts or statutes; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

### **COUNT III – STRICT LIABILITY MANUFACTURING DEFECT**

106. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

107. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, performed

pharmacovigilance, distributed and sold the ParaGard IUD that was implanted into the Plaintiff.

108. The ParaGard IUD implanted in Plaintiff contained a condition or conditions, which Defendants did not intend, at the time the ParaGard IUD left Defendants' control and possession.

109. Plaintiff and Plaintiffs' health care providers used the drug in a manner consistent with and reasonably foreseeable to Defendants.

110. As a result of this condition or these conditions, the product failed to perform as safely as the ordinary consumer would expect, causing injury, when used in a reasonably foreseeable manner.

111. The ParaGard IUD was defectively and/or improperly manufactured, rendering it defective and unreasonably dangerous and hazardous to Plaintiff.

112. As a result of the manufacturing defects, the ParaGard IUD creates risks to the health and safety of the patients that are far more significant and devastating than the risks posed by other products and procedures available to treat the corresponding medical conditions, and which far outweigh the utility of the ParaGard IUD.

113. Defendants have intentionally and recklessly manufactured the ParaGard IUD with wanton and willful disregard for the rights and health of the

Plaintiffs and others, and with malice, placing their economic interests above the health and safety of the Plaintiff and others.

114. As a proximate result of the Defendants' manufacture of the ParaGard IUD, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of care, comfort, and economic damages.

115. The Cooper Defendants are also liable as successors-in-interest under the Hawaii Uniform Fraudulent Transfer Act, Haw. Rev. Stat. §651C-1, *et. seq.*, any other state or federal successor in interest acts or statutes; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

#### **COUNT IV – STRICT LIABILITY FAILURE TO WARN**

116. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

117. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed and sold the ParaGard IUD, including the one implanted into Plaintiff, into the stream of

commerce and in the course of same, directly advertised and marketed the drug to consumers or persons responsible for consumers.

118. At the time Defendants designed set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed and sold the ParaGard IUD into the stream of commerce, Defendants knew or should have known that the drug presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use.

119. Specifically, Defendants knew or should have known that the ParaGard IUD posed a significant risk that one of the arms of the drug could break upon removal, resulting in significant injuries.

120. Defendants had a duty to warn of the risk of harm associated with the use of the drug and to provide adequate warnings concerning the risk the drug could break upon removal, even if implanted properly and even if the drug remained properly in-place.

121. Defendants failed to properly and adequately warn and instruct the Plaintiff and her health care providers with regard to the inadequate research and testing of the ParaGard IUD, and the complete lack of a safe, effective procedure for removal of the ParaGard IUD.

122. The risks associated with the ParaGard IUD are of such a nature that health care providers and users could not have recognized the potential harm.

123. The ParaGard IUD was defective and unreasonably dangerous at the time of its release into the stream of commerce due to the inadequate warnings, labeling and/or instructions accompanying the product, including but not limited to, the implantation and subsequent removal of ParaGard IUD.

124. The ParaGard IUD, when implanted in Plaintiff, was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by the Defendants.

125. The Defendants intentionally, recklessly, and maliciously misrepresented the safety, risks, and benefits in order to advance their own financial interests, with wanton and willful disregard for the rights and health of the Plaintiff.

126. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the ParaGard IUD, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

127. The Cooper Defendants are also liable as successors-in-interest under the Hawaii Uniform Fraudulent Transfer Act, Haw. Rev. Stat. §651C-1, *et. seq.*, any other state or federal successor in interest acts or statutes; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues so triable as a matter of right.

**COUNT V – COMMON LAW FRAUD**

128. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

129. The Defendants have falsely and fraudulently represented and continue to represent to the medical and healthcare community, Plaintiff and her physicians, and/or the public that the ParaGard IUD had been appropriately tested and was found to be safe and effective.

130. The representations made by the Defendants were, in fact, false. When the Defendants made their representations, they knew and/or had reason to know that those representations were false, and they willfully, wantonly, and recklessly disregarded the inaccuracies in their representations and the dangers and health risks to users of the ParaGard IUD.

131. These representations were made by the Defendants with the intent of defrauding and deceiving the medical community, Plaintiff, and the public, and also inducing the medical community, Plaintiff, Plaintiff's physicians, and/or the public, to recommend, prescribe, dispense, and purchase the ParaGard IUD for use as a form

of long-term birth control, all of which evidenced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff.

132. In representations to Plaintiff and/or to her healthcare providers, the Defendants fraudulently concealed and intentionally omitted the following material information:

- a. That the ParaGard IUD was not as safe as other products and procedures available to aid in the long-term prevention of pregnancy;
- b. That the risk of adverse events with the ParaGard IUD was higher than with other products and procedures available for birth control;
- c. The ParaGard IUD was not adequately tested;
- d. That the limited clinical testing for ParaGard IUD revealed a higher risk of adverse events, above and beyond those associated with other products and procedures available for birth control;
- e. That Defendants deliberately failed to follow up on the adverse results from clinical studies and/or formal and informal reports from physicians and/or other healthcare providers and either ignored, concealed and/or misrepresented those findings;
- f. That Defendants were aware of dangers in the ParaGard IUD in addition to and above and beyond those associated with other products and procedures available for birth control;

g. That the ParaGard IUD was defective, and that it caused dangerous and adverse side effects, including but not limited to unacceptable incidence of breakage upon removal;

h. That when the ParaGard IUD needed to be removed, the removal procedure had a very high failure rate and/or needed to be performed repeatedly;

i. That the ParaGard IUD was manufactured negligently;

j. That the ParaGard IUD was manufactured defectively; and

k. That the ParaGard IUD was designed negligently and designed defectively.

133. The Defendants were under a duty to disclose to Plaintiff and her physicians, the defective nature of the ParaGard IUD, including but not limited to, the risk of breakage prior to and upon removal, which could result in permanent injury.

134. The Defendants had sole access to material facts concerning the defective nature of the products and their propensity to cause serious and dangerous side effects and hence, cause dangerous injuries and damage to persons who used the ParaGard IUD, such as Plaintiff.

135. The Defendants' concealment and omissions of material facts concerning the safety of the ParaGard IUD were made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff, Plaintiff's physicians, surgeons and



healthcare providers and to induce them to purchase, prescribe, and/or dispense the ParaGard IUD; and/or to mislead them into reliance upon and cause them to use the ParaGard IUD.

136. At the time these representations were made by Defendants, and at the time Plaintiff and/or her physicians, used the ParaGard IUD, Plaintiff and/or her physicians were unaware of the falsehood of these representations, and reasonably believed them to be true.

137. The Defendants knew and had reason to know that the ParaGard IUD could and would cause severe and grievous personal injury to the users of the product and was inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

138. In reliance upon these false representations, Plaintiff and her physicians were induced to, and did use the ParaGard IUD, thereby causing severe and permanent personal injuries and damages to Plaintiff. The Defendants knew or had reason to know that the Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind the Defendants' concealment and omissions, and that these included material omissions of facts surrounding the use of the ParaGard IUD, as described in detail herein.

139. Plaintiff and her physicians reasonably relied on facts provided by the Defendants which foreseeably and purposefully suppressed and concealed facts that

were critical to understanding the real dangers inherent to the use of the ParaGard IUD.

140. Having knowledge based on the Defendants research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assurances to Plaintiff, the public, and Plaintiff's healthcare providers and physicians, that the ParaGard IUD was safe for use as a means of providing long-term birth control and was as safe or safer than other product and/or procedures available and/or on the market. As a result of Defendants' research and testing, or lack thereof, these Defendants intentionally omitted, concealed and suppressed the dissemination of certain results of testing and research to healthcare professionals, Plaintiff, her physicians, and the public at large.

141. The Defendants had a duty when disseminating information to the public to disseminate truthful information; and a parallel duty not to deceive the public, Plaintiff, and/or her physicians.

142. The information distributed to the public, the medical community, Plaintiff and her physicians by the Defendants included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, professional literature, reports, press releases, advertising campaigns, television commercials, print advertisements, and/or other commercial media, and contained

material representations which were false and misleading, as well as omissions and concealments of the truth about the dangers of the use of the ParaGard IUD.

143. These representations, and others made by the Defendants, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist, and were made recklessly and without regard to the true facts.

144. The Defendants recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of the ParaGard IUD to Plaintiff, her physicians and the public at large, for the purpose of influencing the sales of products known to be dangerous and defective, and/or not as safe as other alternatives.

145. At the time the representations were made, Plaintiff and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of the ParaGard IUD.

146. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of the Defendants, nor would Plaintiff with reasonable diligence have discovered the true facts about the Defendant's misrepresentations at the time when the ParaGard IUD was surgically implanted into her.

147. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of the ParaGard IUD, neither Plaintiff nor her physician would not have purchased, used, or relied on Defendants' representations and omissions concerning the ParaGard IUD.

148. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the ParaGard IUD, Plaintiff has been seriously injured, and sustained severe and permanent injury, pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

149. The Cooper Defendants are also liable as successors-in-interest under the Hawaii Uniform Fraudulent Transfer Act, Haw. Rev. Stat. §651C-1, *et. seq.*, any other state or federal successor in interest acts or statutes; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

#### **COUNT VI – NEGLIGENT MISREPRESENTATION**

150. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

151. At relevant times, Defendants negligently provided Plaintiff, her healthcare providers, and the general medical community with false or incorrect information or omitted or failed to disclose material information concerning the ParaGard IUD, including, but not limited to, misrepresentations regarding the safety of the ParaGard IUD.

152. The information distributed by the Defendants to the public, the medical community, the Plaintiff and her healthcare providers, including advertising campaigns, labeling materials, print advertisements, commercial media, was false and misleading and contained omissions and concealment of truth about the dangers of the ParaGard IUD.

153. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiffs' health care providers; to falsely assure them of the quality of the ParaGard IUD and to induce the public and medical community, including Plaintiff and her healthcare provider to request, recommend, prescribe, implant, purchase and continue to use the ParaGard IUD.

154. The Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, medical drug manufacturers, Plaintiff, her healthcare providers and the public, that the ParaGard IUD had been tested and found to be safe and effective for long term birth control.

155. The representations made by the Defendants were, in fact, false. The ParaGard IUD was not safe for human use in its intended and reasonably foreseeable manner. Use of the ParaGard IUD is dangerous as there is a risk that it may fracture upon removal cause significant injury.

156. In reliance upon the false and negligent misrepresentations and omissions made by the Defendants, Plaintiff and Plaintiff's healthcare providers were induced to, and did use the ParaGard IUD, thereby causing Plaintiff to endure severe and permanent injuries.

157. Defendants knew and had reason to know that the Plaintiff, Plaintiff's healthcare providers, and the general medical community did not have the ability to determine the true facts which were intentionally and/or negligently concealed and misrepresented by the Defendants.

158. Plaintiff and her healthcare providers would not have recommended, and implanted ParaGard IUD had the true facts not been concealed by the Defendants.

159. Defendants had sole access to the material facts concerning the defective nature of the ParaGard IUD and its propensity to cause serious and dangerous side injuries.

160. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff was implanted with the ParaGard IUD,

Plaintiff and her healthcare providers were unaware of Defendants' negligent misrepresentations and omissions.

161. The Defendants failed to exercise ordinary care in making representations concerning the ParaGard IUD while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because the Defendants negligently misrepresented the ParaGard IUD's high risk of unreasonable and dangerous adverse side effects.

162. The Defendants breached their duty to Plaintiff, her physicians, and the medical and healthcare community, by representing that the ParaGard IUD has no serious side effects different from older generations of similar products or procedures.

163. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the misrepresentations and omissions made by the Defendants, where they concealed and misrepresented facts that were critical to understanding the true dangers inherent in the use of the ParaGard IUD.

164. Plaintiff and Plaintiff's healthcare providers' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiffs injuries.

165. The Defendants knew, and had reason to know, that the ParaGard IUD had been insufficiently tested, or had not been tested at all, that the products lacked

adequate and accurate warnings, that they created a high risk, and/or higher than acceptable risk, and/or higher than reported risk that they represented a risk of adverse side effects, including, pain and suffering, surgery to remove the product, and other severe and personal injuries, which are permanent and lasting in nature.

166. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the ParaGard IUD, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

167. The Cooper Defendants are also liable as successors-in-interest under the Hawaii Uniform Fraudulent Transfer Act, Haw. Rev. Stat. §651C-1, *et. seq.*, any other state or federal successor in interest acts or statutes; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

#### **COUNT VII – BREACH OF EXPRESS WARRANTY**

168. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.



169. At relevant times, Defendants intended that the ParaGard IUD be used in the manner that Plaintiff used it and Defendants expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other treatments for long-term birth control, and that they were adequately tested and fit for their intended use.

170. At relevant times, Defendants were aware that consumers, including Plaintiff, would use the ParaGard IUD; which is to say that Plaintiff was a foreseeable user of the ParaGard IUD.

171. Plaintiff and/or her implanting physicians were, at all relevant times, in privity with the Defendants.

172. ParaGard IUD was expected to reach and did in fact reach its ultimate consumer, including Plaintiff and her implanting physicians, without substantial change in the condition in which it was manufactured and sold by the Defendants.

173. The Defendants breached various express warranties with respect to the ParaGard IUD including the following particulars:

- a. The Defendants represented to Plaintiff and her physicians and healthcare providers through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the ParaGard IUD was safe, and fraudulently withheld and

concealed information about the substantial risks of serious injury associated with using the ParaGard IUD;

b. The Defendants represented to Plaintiff and her physicians and healthcare providers that the ParaGard IUD was as safe, and/or safer than other alternative procedures and drugs and fraudulently concealed information, which demonstrated that the ParaGard IUD was not safer than alternatives available on the market; and

c. The Defendants represented to Plaintiff and her physicians and healthcare providers that the ParaGard IUD was more efficacious than other alternatives and fraudulently concealed information regarding the true efficacy of the products.

174. In reliance upon the Defendants' express warranties, Plaintiff was implanted with the ParaGard IUD as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by the Defendants.

175. At the time of making such express warranties, the Defendants knew or should have known that the ParaGard IUD does not conform to these express representations because the ParaGard IUD was not safe and had numerous side effects, many of which the Defendants did not accurately warn about, thus making the ParaGard IUD unreasonably unsafe for its intended purpose.

176. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and her physicians, relied upon the representations and warranties of the Defendants in connection with use, recommendation, description, and/or dispensing of the ParaGard IUD.

177. The Defendants breached their express warranties to Plaintiff in that the ParaGard IUD was not of merchantable quality, safe and/or fit for its intended uses, nor was it adequately tested.

178. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the ParaGard IUD, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

179. The Cooper Defendants are also liable as successors-in-interest under the Hawaii Uniform Fraudulent Transfer Act, Haw. Rev. Stat. §651C-1, *et. seq.*, any other state or federal successor in interest acts or statutes; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

**COUNT VIII – BREACH OF IMPLIED WARRANTY**

180. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

181. At relevant and material times, Defendants manufactured, distributed, advertised, promoted, and sold the ParaGard IUD.

182. At relevant times, Defendants intended that the ParaGard IUD be implanted for the purposes, and in the manner, that Plaintiff or her physicians or surgeons used it and the Defendants impliedly warranted each ParaGard IUD to be of merchantable quality, safe and fit for such use, and to have been adequately tested.

183. Defendants were aware that consumers, including Plaintiff or her physicians or surgeons would implant the ParaGard IUD in the manner described by the instructions for use and that Plaintiff was the foreseeable user of the ParaGard IUD.

184. Plaintiff and/or her physicians and surgeons were at all relevant times in privity with Defendants.

185. The Defendants' ParaGard IUD was expected to reach and did in fact reach consumers, including Plaintiff and/or her physicians and surgeons, without substantial change in the condition in which they manufactured and sold by Defendants.

186. Defendants breached various implied warranties with respect to the ParaGard IUD, including the following particulars:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, medical literature, and regulatory submissions that the ParaGard IUD was safe and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the ParaGard IUD;

b. Defendants represented that the ParaGard IUD was safe, and/or safer than other alternative drugs or procedures and fraudulently concealed information, which demonstrated that the ParaGard IUD was not as safe or safer than alternatives available on the market; and

c. Defendants represented that the ParaGard IUD was more efficacious than other alternative treatments and fraudulently concealed information, regarding the true efficacy of the ParaGard IUD.

187. In reliance upon Defendants' implied warranties, Plaintiff and/or her implanting physicians and surgeons used the ParaGard IUD as prescribed in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

188. Defendants breached their implied warranties to Plaintiff and/or her implanting physicians and surgeons in that the ParaGard IUD was not of

merchantable quality, safe and fit for its intended use, or adequately tested, in violation of common law principles.

189. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the ParaGard IUD, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

190. The Cooper Defendants are also liable as successors-in-interest under the Hawaii Uniform Fraudulent Transfer Act, Haw. Rev. Stat. §651C-1, *et. seq.*, any other state or federal successor in interest acts or statutes; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

#### **COUNT IX – VIOLATION OF CONSUMER PROTECTION LAWS**

191. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

192. Plaintiff purchased and used the ParaGard IUD primarily for personal use thereby suffering ascertainable losses, as a result of the Defendants' actions in violation of the consumer protection laws.

193. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff and her physicians would not have purchased and/or paid for the ParaGard IUD and would not have incurred related medical costs and injury.

194. The Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for the ParaGard IUD, that was implanted into her, and that would not have been paid for had the Defendants not engaged in unfair and deceptive conduct.

195. Unfair methods of competition of deceptive acts or practices that were proscribed by law, including the following:

- a. Representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;
- b. Advertising goods or services with the intent not to sell them as advertised; and
- c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion and/or misunderstanding.

196. Plaintiff was injured by the cumulative and indivisible nature of the Defendants' conduct. The cumulative effect of the Defendants' conduct directed at

patients, physicians and consumers, including the Plaintiff and her physicians, was to create demand for and promote the sale of ParaGard IUD. Each aspect of the Defendants' conduct combined to artificially create sales of the ParaGard IUD.

197. The Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the ParaGard IUD.

198. Had the Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the ParaGard IUD, and would not have incurred related medical costs.

199. The Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff and her physicians, constituted unfair and deceptive acts and trade practices in violation of the state and Federal consumer protection statutes.

200. The Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state and Federal consumer protection statutes, including but not limited to the Uniform Deceptive Trade Practices Act, Haw. Rev. Stat. § 481A-1, *et. seq.*

201. The Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation



under the statute listed above to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, the Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

202. The Defendants engaged in fraudulent behavior regarding the transfer and/or sale of assets to Cooper Defendants in 2017. Cooper Defendants knew or should have reasonably known that the transfer of assets was done in a manner consistent with and in an effort to, deceive potential creditors.

203. Pursuant to the terms of the asset purchase agreement, Teva Women's Health, Inc., claims to maintain liability for all ParaGard IUD placed prior to the execution of the asset purchase agreement in September of 2017. However, Teva Women's Health, Inc., converted to Teva Women's Health, LLC and sold off all of its assets.

204. Cooper Defendants knew or reasonably should have known that Teva Defendants converted Teva Women's Health, Inc., into Teva Women's Health, LLC after selling off or moving all assets from Teva Women's Health, Inc.

205. Therefore, Cooper Defendants knew or reasonably should have known that Teva Defendants shuffling of assets and subsequent conversions were done to

thwart potential creditors in violation of the Uniform Deceptive Trade Practices Act, Haw. Rev. Stat. § 481A-1, *et. seq.* and Federal consumer protection laws.

206. The Defendants violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the ParaGard IUD was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials and product labeling.

207. The actions and omissions of the Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

208. The Defendants had actual knowledge of the defective and dangerous condition of the ParaGard IUD and failed to take any action to cure such defective and dangerous conditions.

209. Plaintiff and her implanting physicians and surgeons relied upon the Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform.

210. The Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constitute unfair and deceptive acts and practices.

211. By reason of the unlawful acts engaged by the Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

212. As a proximate result of the Defendants' design, manufacture, marketing, sale and/or distribution of the ParaGard IUD, Plaintiff has been injured catastrophically, and sustained severe and permanent pain, suffering, disability, and impairment, loss of enjoyment of life, loss of reproductive health, comfort, and economic damages.

213. The Cooper Defendants are also liable as successors-in-interest under the Hawaii Uniform Fraudulent Transfer Act, Haw. Rev. Stat. §651C-1, *et. seq.*, any other state or federal successor in interest acts or statutes; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

**COUNT X – GROSS NEGLIGENCE**

214. Plaintiff realleges and incorporates by reference every allegation of this Complaint as if each were set forth fully and completely herein.

215. The wrongs done by the Defendants were aggravated by the kind of malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, for which the law would allow, and which Plaintiff will seek at the appropriate time under governing law for the imposition of exemplary damages, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included material representations that were false, with Defendants, knowing that they were false or with reckless disregard as to the truth and as a positive assertion, with the intent that the representation is acted on by Plaintiff.

216. Plaintiff and her physicians relied on the representations of Defendants and suffered injury as a proximate result of this reliance.

217. Plaintiff therefore will seek to assert claims for exemplary damages at the appropriate time under governing law in an amount within the jurisdictional limits of the Court.

218. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused that injuries to Plaintiff. In that regard, Plaintiff will seek exemplary damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

219. The Cooper Defendants are also liable as successors-in-interest under the Hawaii Uniform Fraudulent Transfer Act, Haw. Rev. Stat. §651C-1, *et. seq.*, any other state or federal successor in interest acts or statutes; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

#### **COUNT XI – PUNITIVE DAMAGES**

220. Plaintiff incorporates by reference each and every allegation contained in the preceding paragraphs as though fully set forth herein.

221. At times material hereto, Defendants knew or should have known that their ParaGard IUD, as designed, manufactured, assembled, sold and/or distributed was inherently dangerous.

222. At times material hereto, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of their ParaGard IUD.

223. Defendants' misrepresentations included knowingly withholding material information from the public and consumers alike, including Plaintiff, concerning the safety of the ParaGard IUD.

224. At times material hereto, Defendants knew and recklessly disregarded the fact that their ParaGard IUD could cause serious, disabling, and permanent injuries to individuals such as Plaintiff.

225. Notwithstanding the foregoing, Defendants continued to aggressively market and promote their ParaGard IUD, without disclosing the risks.

226. As a proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of their consumers, Plaintiff suffered severe and permanent physical and emotional injuries, endured pain and suffering, and has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future.

227. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

228. The Cooper Defendants are liable as successors-in-interest under the Hawaii Uniform Fraudulent Transfer Act, Haw. Rev. Stat. §651C-1, *et. seq.*, any other state or federal successor in interest acts or statutes; and the Federal Consumer Protection Act pursuant to a fraudulent conveyance or transfer of assets.

WHEREFORE, Plaintiff demands judgment against the Defendants, jointly and severally, for compensatory damages, for punitive damages and for costs, in an as yet unliquidated sum in excess of \$75,000.00, and such other relief as this Court deems just and for a trial by jury on all issues as triable as a matter of right.

### **PRAYER FOR RELIEF**

So far as the law and this Court allows, Plaintiff demands judgment against each Defendant on each count as follows:

A. All available compensatory damages for the described losses with respect to each cause of action;

B. Past and future medical expenses, as well as the cost associated with past and future life care;

- C. Past and future lost wages and loss of earning capacity;
- D. Past and future emotional distress;
- E. Consequential damages;
- F. All available noneconomic damages, including without limitation pain, suffering, and loss of enjoyment of life;
- G. Punitive damages with respect to each cause of action;
- H. Reasonable attorneys' fees where recoverable;
- I. Costs of this action;
- J. Pre-judgment and all other interest recoverable; and
- K. Such other additional, further, and general relief as Plaintiff may be entitled to in law or in equity as justice so requires.

DATED: Honolulu, Hawaii, October 14, 2020

/s/ Michael L. Lam

MICHAEL L. LAM, ESQ.

STEVEN E. TOM, ESQ.

**Case Lombardi & Pettit**

/s/ Randi Kassin

RANDI KASSAN, ESQ.

**Sanders Phillips Grossman**

*(pro hac vice forthcoming)*

Attorneys for Plaintiff

**JONELLE KIRKPATRICK**



UNITED STATES DISTRICT COURT  
DISTRICT OF HAWAII

JONELLE KIRKPATRICK,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,  
INC.; TEVA WOMEN'S HEALTH,  
INC. d/b/a TEVA WOMEN'S  
HEALTH, LLC; TEVA WOMEN'S  
HEALTH, LLC; THE COOPER  
COMPANIES, INC.; and  
COOPERSURGICAL, INC.,

Defendants.

Case No.:

**DEMAND FOR JURY TRIAL**

**DEMAND FOR JURY TRIAL**

Plaintiff JONELLE KIRKPATRICK, through undersigned counsel, demands  
a trial by jury on all claims in this action.

DATED: Honolulu, Hawaii, October 14, 2020

/s/ Michael L. Lam

MICHAEL L. LAM, ESQ.

STEVEN E. TOM, ESQ.

**Case Lombardi & Pettit**

/s/ Randi Kassin

RANDI KASSAN, ESQ.

**Sanders Phillips Grossman**

*(pro hac vice forthcoming)*

Attorneys for Plaintiff

**JONELLE KIRKPATRICK**

UNITED STATES DISTRICT COURT  
DISTRICT OF HAWAII

JONELLE KIRKPATRICK,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,  
INC.; TEVA WOMEN'S HEALTH,  
INC. d/b/a TEVA WOMEN'S  
HEALTH, LLC; TEVA WOMEN'S  
HEALTH, LLC; THE COOPER  
COMPANIES, INC.; and  
COOPERSURGICAL, INC.,

Defendants.

Case No.:

**SUMMONS**

**SUMMONS**

STATE OF HAWAII  
TO THE ABOVE-NAMED DEFENDANTS:

You are hereby summoned and required to file with the court and serve upon MICHAEL L. LAM of Case Lombardi & Pettit, Plaintiffs' attorney, whose address is Pacific Guardian Center, Mauka Tower, 737 Bishop Street, Suite 2600, Honolulu, Hawaii 96813, an answer to the Complaint which is herewith served upon you, within twenty-one (21) days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the Complaint.

THIS SUMMONS SHALL NOT BE PERSONALLY DELIVERED BETWEEN 10:00 P.M. AND 6:00 A.M. ON PREMISES NOT OPEN TO THE GENERAL PUBLIC, UNLESS A JUDGE OF THE ABOVE-ENTITLED COURT

PERMITS, IN WRITING ON THIS SUMMONS, PERSONAL DELIVERY DURING THOSE HOURS.

A FAILURE TO OBEY THIS SUMMONS MAY RESULT IN AN ENTRY OF DEFAULT AND DEFAULT JUDGMENT AGAINST THE DISOBEYING PERSON OR PARTY.

DATED: Honolulu, Hawaii \_\_\_\_\_.

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CLERK OF THE ABOVE-ENTITLED COURT